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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA,) Case No. 18-CR-00258 EJD
) Plaintiff,
)
) UNITED STATES' OMNIBUS RESPONSE TO
) DEFENDANT HOLMES' MOTIONS TO
) RECONSIDER OR CLARIFY THE COURT'S
) ORDER ON MOTIONS *IN LIMINE* (ECF NOS.
) 892, 895, 897, 899)
)
) Date: August 20, 2021
) Time: 10:00 a.m.
) Court: Hon. Edward J. Davila
v.
ELIZABETH HOLMES,
Defendant.

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INTRODUCTION

On the eve of trial, Defendant Elizabeth Holmes has filed four motions that essentially ask the Court to reconsider several of its rulings on motions *in limine* that were unfavorable to her or to clarify rulings that the Court explicitly denied or deferred. *See* Ms. Holmes' Renewed Motion to Exclude Certain News Articles, ECF No. 895 ("895 Motion"); Ms. Holmes' Motion to Partially Redact Government Agency Reports, ECF No. 897 ("897 Motion"); Ms. Holmes' Renewed Motion to Exclude Certain Doctor Testimony, ECF No. 899 ("899 Motion"); Ms. Holmes' Motion to Strike Expert Opinion Testimony of Dr. Kingshuk Das, ECF No. 892 ("892 Motion").

The government respectfully requests the Court deny outright or defer ruling on these motions, given that they are at best premature considering the trial has not even begun and the substance has largely been decided by the Court's order on the parties' motions *in limine*.

BACKGROUND

Defendant Elizabeth Holmes filed over 250 pages of motions *in limine* (in addition to supporting materials) seeking to exclude large swaths of what the Court ultimately deemed relevant evidence. *See generally* ECF Nos. 560–587, 798. The government filed 25 pages addressing its requested motions *in limine*. ECF No. 588. The parties also filed responses and replies addressing all of the above. ECF Nos. 659–682, 704–727. The Court held a three-day hearing to address the voluminous motions *in limine*, and ultimately issued a detailed 100-page order addressing each in turn (“MIL Order”). ECF Nos. 780, 783, 786, 798 (Court’s Order re: Motions *In Limine* (“MIL Order”)), *available at United States v. Holmes*, No. 5:18-CR-00258-EJD-1, 2021 WL 2044470 (N.D. Cal. May 22, 2021); ECF No. 792, 5/4/2021 Hearing Transcript (“5/4 Tr.”); ECF No. 793, 5/5/2021 Hearing Transcript (“5/5 Tr.”); ECF No. 794, 5/6/2021 Hearing Transcript (“5/6 Tr.”). As relevant here, the Court held that: (1) Defendant’s motion to exclude news articles as to unidentified news articles was premature because a one-by-one analysis was required; (2) the FDA and CMS Reports were relevant, not unduly prejudicial, not 404(b) evidence, and not hearsay; (3) testimony of Theranos employees may be admitted based on how closely connected they were to Defendant Holmes and the government established a sufficient nexus for a September 2015 letter from Theranos to CMS; (4) physicians may testify about inaccurate Theranos test results they received as factual matters not expert opinions; and (5) testimony

1 from former Theranos lab directors regarding mathematical formulas used to arrive at the conclusion
 2 that Theranos's technology was not working sufficiently to use for patient testing are not providing
 3 expert testimony but rather percipient testimony in light of their background expertise. *See* MIL Order
 4 at 10–20, 25–27, 39–44, 47–54, 70–72, 75–78, 90, 94–97. Jury selection for the trial against Defendant
 5 Holmes is set to begin August 31, 2021.

6 Now, less than one month before the trial against her is set to begin, Defendant Holmes has filed
 7 additional motions or “renewed motions” to exclude certain evidence or testimony—all of which
 8 address topics covered by this Court’s 100-page MIL Order.

9 **ARGUMENT**

10 **I. DEFENDANT’S MOTIONS ARE PREMATURE AND THE COURT SHOULD DEFER
 11 PROVIDING THE UNNECESSARY BLANKET RULINGS SHE SEEKS**

12 Each of Defendant’s currently pending four motions essentially ask the Court to reconsider or
 13 clarify its detailed rulings made in its 100-page MIL Order (ECF No. 798). District courts routinely
 14 deny motions to reconsider orders on motions *in limine* when no new facts or change in law has
 15 occurred since the court’s initial ruling. *See, e.g., Madrigal v. Allstate Indem. Co.*, No. 14-CV-4242-SS,
 16 2015 WL 12748277, at *3 (C.D. Cal. Nov. 5, 2015) (finding neither party presented “sufficient grounds
 17 to warrant reconsideration of” the court’s prior MIL order); *Morris v. Long*, No. 08-CV-01422-AWI,
 18 2012 WL 3276938, at *7 (E.D. Cal. Aug. 9, 2012) (where Defendant “provide[d] no compelling reason
 19 why the Court should reconsider its previous [MIL] ruling” the court held the MIL remained granted as
 20 it had ruled previously), *clarified on denial of reconsideration*, 2012 WL 3528015 (E.D. Cal. Aug. 14,
 21 2012), *and aff’d*, 592 F. App’x 579 (9th Cir. 2015).

22 The government urges the Court to adopt the same approach here: to maintain its rulings as
 23 expressed in the MIL Order and defer—or deny outright—Defendant’s 895, 897, 899, and 892 Motions.
 24 The parties extensively briefed several of the issues Defendant renews in the present motions, the Court
 25 heard argument on each at length, and nothing has changed in the little over two months since the Court
 26 issued its detailed findings in its MIL Order. The government understood the Court’s MIL Order
 27 denying without prejudice or deferring matters to signal an intention to revisit those issues if necessary
 28 when relevant evidence was actually offered at trial—taking into account the context and foundation laid

1 for each exhibit. Because that approach promises to be more efficient and precise than issuing blanket
 2 orders without the benefit of trial context, Defendant's motions are premature.

3 **II. DEFENDANT'S MOTION TO EXCLUDE ADDITIONAL NEWS ARTICLES IS
 4 PREMATURE AND POTENTIALLY UNNECESSARY**

5 As a clear example of a premature and potentially unnecessary request at this stage in the case,
 6 Defendant's 895 Motion renews Defendant's request to exclude seven news articles that she did not
 7 identify for the Court at the motion *in limine* stage. 895 Mot. at 3–4. But her motion glosses over the
 8 fact that the Court resisted her request to issue a "blanket order" over all articles included on the
 9 government's witness list and instead conducted a detailed analysis of each article Defendant submitted
 10 with her motion *in limine* and did not wholesale exclude all media articles. MIL Order at 39–44. The
 11 government submits the Court should similarly deny Defendant's renewed motion seeking the same type
 12 of blanket order this Court has already rejected.

13 Moreover, the Court specifically held it would "be premature to address a motion in limine when
 14 the defendant has not identified any 'particular objectionable statement' she seeks to preclude." *Id.* at 40
 15 (citation omitted). Defendant did not challenge these articles directly in her motion *in limine* and
 16 Defendant's 895 Motion does not fill this void as it only references one line each from five of the seven
 17 attached articles—and identifies no statements from the remaining two articles. *See* 895 Mot. at 3–4
 18 (quoting one line from the first five of seven exhibits). Defendant's 895 Motion generically asserts
 19 these additional seven articles should also fall under the Court's analysis excluding six articles without
 20 providing an individualized analysis as the Court walked through in its original ruling. *See* MIL Order
 21 at 39–44. Thus, Defendant has not overcome the bar set in the Court's initial MIL Order and does not
 22 provide the kind of detailed analysis the Court would need to address these additional articles (which, of
 23 course, Defendant could have submitted or discussed with its original motion *in limine*, as well).

24 To the extent it aids Defendant in trial preparation, the government commits to not referencing
 25 these seven articles in its opening statement and will provide advance notice to the Court and Defendant
 26 if it intends to introduce any of these seven articles as exhibits during its case-in-chief. However, the
 27 government maintains that a blanket order such as Defendant seeks is unnecessary and premature, just as
 28 it was shortly over two months ago.

1 Furthermore, Defendant's 895 Motion does not consider the reasons why these seven articles
 2 should be subject to a different analysis than the October 2015 *Wall Street Journal* piece. Specifically,
 3 these articles may be relevant in connection with Defendant's efforts hiring people to aid in responding
 4 to the media after the *Wall Street Journal*'s exposé of Defendant's fraud. Additionally, potential
 5 witnesses beyond the authors could verify statements Defendant made in some of those articles, which
 6 could be another avenue to avoid the double hearsay problem identified by the Court in its MIL Order.
 7 *See* MIL Order at 43–44. Alternatively, some articles may also be useful simply for the effect on the
 8 reader seeking to understand the publicly available information and Theranos's response to it. *See id.* at
 9 42. Without waiting for evidence to be presented at trial, Defendant simply asks the Court to do what it
 10 resisted previously and order a blanket ruling with minimal information on these seven articles. *Cf. id.*
 11 at 40. The government urges the Court to resist this request and maintain its prior MIL Order.

12 **III. DEFENDANT'S MOTION TO PARTIALLY REDACT AGENCY REPORTS IS
 13 PREMATURE AND OVERBROAD**

14 Defendant's 897 Motion seeks to relitigate motions *in limine* she filed (ECF Nos. 573, 574) that
 15 the Court ruled against her on—under the guise of providing redactions consistent with the Court's MIL
 16 Order. She seeks to redact the summary of each section of two FDA Reports that the Court permitted,
 17 and she seeks to redact more than three-quarters of the CMS Report that the Court expressly allowed to
 18 come in at trial pursuant to one of the government's motions *in limine*. *See* ECF Nos. 898-4, 898-5,
 19 898-6; MIL Order at 10–20. In essence, Defendant is asking the Court to reconsider its unfavorable
 20 rulings against her position on the agency reports or, alternatively, admit her proposed redacted versions
 21 that omit most all relevant information but for generic statements and standards the agencies use to
 22 evaluate laboratories. *See* 897 Mot. at 5, 9. Defendant did not meet and confer with the government
 23 regarding these redactions, despite the invitation to do so at the MIL hearing. *See* 5/5 Tr. at 79:10–24.
 24 The government submits Defendant's proposed redactions are vastly overbroad and contravene the
 25 rationale expressed in the Court's MIL Order, and thus the government requests the Court deny
 26 Defendant's 897 Motion outright or, at least, defer ruling on it until after foundational evidence is
 27 presented at trial.
 28

1 Defendant filed six separate motions *in limine* seeking to exclude various aspects of regulatory-
 2 related material, including correspondence and interactions between Theranos and regulatory agencies,
 3 reports of agencies (including the FDA and CMS Reports discussed in 897 Motion), and sanctions,
 4 settlements, and remedial actions taken as a result of regulatory findings. *See* ECF Nos. 569, 572–575.
 5 The parties argued these topics for the better part of one day of the three-day hearing. 5/5 Tr. at 40–80,
 6 100–131. The Court substantially sided with the government by denying or deferring exclusion of the
 7 vast majority of materials covered by Defendant’s regulatory-related motions and by granting the
 8 Government’s motion to admit the CMS Report at trial (ECF No. 588 at 15–17). MIL Order 10–20, 25–
 9 27, 30–39, 71–72, 90. The Court’s prior holdings are described in more detail as relevant below.

10 FDA. As relevant to the FDA-related evidence challenged in Defendant’s 897 Motion, the Court
 11 held that the “FDA inspection evidence” that Defendant challenged—which included much more than
 12 just the FDA Reports¹—was relevant, “more probative than prejudicial,” not 404(b) character evidence,
 13 and not hearsay because “the FDA inspection was a matter observed while under a legal duty to report.”
 14 MIL Order at 10–16 (internal quotation omitted). The Court held that the FDA Reports consist “largely
 15 of observations” and while there “are portions of the report that go beyond mere observations and
 16 include some level of analysis by FDA inspectors” those “portions comprise only a minor portion of the
 17 report.” *Id.* at 14. Part of the Court’s rationale in determining that these statements were not hearsay is
 18 because the FDA inspectors “do not appear to have been making observations in an adversarial setting
 19 that raises doubts about the reliability of the observations.” *Id.* at 15.

20 The Court’s findings regarding the FDA Reports continues to be true and apply to the portions
 21 Defendant seeks to redact. Defendant seeks to redact the summary of each observation, but these are not
 22 statements that fall within the Court’s limited category of statements that “include some level of analysis
 23 by FDA inspectors.” *Compare* ECF Nos. 898-4, *and* 898-5, *with* MIL Order at 14–15. For example,
 24

25 ¹ Defendant asserts that she intends to object to evidence beyond the FDA Reports at trial. 897 Mot. at
 26 5 n.1. The government notes that any such objections should be viewed as a motion to reconsider the
 27 Court’s MIL Order regarding the FDA Inspection Evidence, which covered a broad swath of material
 28 beyond just the reports, as the Court summarized on page 10 of its order. *See* MIL Order at 10–16.
 Rather, the Court specified that Defendant may identify “certain exhibits within this collection of
 evidence and *make new arguments* as to why these particular exhibits should be excluded.” *Id.* at 16
 (emphasis added).

1 one of Defendant's proposed redactions summarizes that “[q]uality audits have not been performed” and
 2 is followed by details describing the inconsistency of Theranos's audit protocol and supporting the
 3 observation. ECF No. 898-5 at 5. Similar examples are littered throughout Defendant's proposed
 4 redactions: “The evaluation of potential suppliers was not documented”; “Software validation activities
 5 and results . . . have not been documented”; “Complaints involving the possible failure of a device to
 6 meet any of its specifications were not reviewed, evaluated, and investigated where necessary”; and
 7 “Documents were not reviewed and not approved by designated individual(s) prior to issuance.” *Id.* at
 8 3–4; ECF No. 898-4 at 6. These are quintessential observations and do not involve “analysis of FDA
 9 inspectors”—they are simply concluding in plain English what is summarized below in more detail with
 10 more technical jargon. Thus, these redactions are unnecessary and do not fall within the Court's
 11 intention to redact limited portions (if any). *See* MIL Order at 14–16; *see also* 5/5 Tr. at 112:6–118:13.²
 12 And, of course, any redactions are premature because the government has not yet identified which
 13 portions of the FDA Reports it intends to enter into evidence. The Court could defer ruling on this
 14 motion until such time. Also, the Court should defer ruling on the claimed hearsay of a Theranos
 15 employee for the reasons stated below with respect to the CMS Report. *Contra* 897 Mot. at 6–7.

16 **CMS.** Contrary to Defendant's assertion that the January 2016 Letter from CMS to Theranos
 17 transmitting the CMS Report is “new[]” and not covered by the Court's MIL Order (897 Mot. at 7),
 18 Defendant sought to exclude the letter along with the CMS Report—collectively labeling them the
 19 “January 2016 CMS Report”—in her original motions *in limine*. ECF Nos. 574 at 6, 581-1. Indeed, the
 20 Court quoted from and summarized the January 2016 CMS Letter, and included it in the category of
 21 “CMS survey findings and sanctions” that the Court reviewed in ruling on the parties' overlapping
 22

23 ² The cases Defendant cites are not to the contrary. 897 Mot. at 6. Defendant cites the same cases relied
 24 on by the Court in its MIL Order to determine that most of the statements by FDA and CMS inspectors
 25 were not in a law enforcement capacity. MIL Order at 14 (citing cases and describing fact patterns).
 26 These cases note that items in a medical report drawn from a police report—or that are otherwise
 27 prepared in an adversarial setting—may cross the line for purposes of the public records exception to
 28 hearsay, but none of the statements Defendant identifies comes even close to that standard. *See, e.g.*,
United States v. Rosa, 11 F.3d 315, 332–33 (2d Cir. 1993) (statements admissible under hearsay
 exception because law enforcement prohibition “should not be applied in the context of reports of public
 officials having different responsibilities”); *United States v. Hansen*, 583 F.2d 325, 333 (7th Cir. 1978)
 (city building inspectors are not law enforcement for hearsay purposes).

1 motions. MIL Order at 17–18; *see also id.* at 31.³ The Court ultimately held that the CMS evidence—
 2 including the letter—was relevant, “more probative than prejudicial,” and not hearsay. *Id.* at 16–20.
 3 Defendant discussed with the Court at length during the MIL hearing why she believed the January 2016
 4 CMS Letter was hearsay. *See* 5/5 Tr. at 54:15–61:16, 71:6–76:10. The Court noted that Defendant took
 5 particular issue with references to “CMS’s finding of ‘immediate jeopardy’”—“which is the most severe
 6 finding that a CMS inspector can make” (5/5 Tr. at 45:11–12)—but held the phrase did not raise unfair
 7 prejudice concerns. MIL Order at 19. The Court denied Defendant’s motion and, as with the broad
 8 category of FDA evidence, left the door open for the parties to make *new arguments* about certain
 9 exhibits—but Defendant’s present arguments simply rehash the same hearsay arguments she made three
 10 months ago that the Court subsequently rejected. *Compare* 897 Mot. at 7, *with* MIL Order at 13–16, 20.

11 Defendant’s arguments for her widespread redactions of the CMS Letter and Report similarly
 12 lack merit when compared with the Court’s MIL Order. 897 Mot. at 7–8. First, Defendant suggests
 13 redactions to the January 2016 CMS Letter that are untethered to her purported rationales and include a
 14 suggested redaction of the headline of the letter: “Condition Level Deficiencies – Immediate
 15 Jeopardy[.]” ECF No. 898-6 at 2. But the Court explicitly reviewed Defendant’s challenges to the
 16 phrase “immediate jeopardy” and rejected them. *See* MIL Order at 19. Defendant also seeks to redact
 17 paragraphs describing the process when an immediate jeopardy finding is made and next steps
 18 purportedly as “beyond mere observations.” *Id.* at 2–3. Defendant also seeks to redact CMS
 19 observations such as: “Based on laboratory personnel interviews and pre-analytic policies and
 20 procedures record review . . . the laboratory failed to establish written policies and procedures for an
 21 ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the
 22 laboratory’s preanalytic systems when received patient specimens did not meet the laboratory’s criteria
 23 for acceptability.” ECF No. 898-6 at 11. However, these are akin to the non-law enforcement
 24 observations and reports that the Court held were not hearsay and Defendant’s proposed redactions on
 25 this basis should be rejected. *See* MIL Order 13–16; *United States v. Orozco*, 590 F.2d 789, 793

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³ And, of course, Defendant generically referenced correspondence with CMS or regulators in several of her other motions *in limine*, with no better success. *See* MIL Order at 25–27, 30–39, 71–72.

1 (9th Cir. 1979) (not hearsay where recording license plate numbers in course of his duties and not in an
 2 adversarial context).

3 Second, Defendant provides redactions of assays not included in the government's Bill of
 4 Particulars, but ignores her representation to the Court that she was "not seeking a blanket ruling
 5 precluding any mention of other tests offered by Theranos that were not included in the Government's
 6 Bill of Particulars[.]" MIL Order at 78. The government insisted it should be permitted to reference
 7 assays not within the Bill of Particulars as long as it was not "attacking their accuracy and reliability,"
 8 and Defendant conceded that "there may be permissible purposes for the introduction of such
 9 evidence[.]" *Id.* at 79. Indeed, the Court expressly held that the "Government may still introduce
 10 evidence or testimony about tests not listed in the Bill of Particulars for purposes unrelated to the
 11 accuracy and reliability of those tests" if it provides advance notice to Defendant. *Id.* at 80.
 12 Nevertheless, Defendant seeks in her 897 Motion to wholesale redact every reference to an assay not
 13 listed on the Bill of Particulars—seeking exactly the blanket ruling she disavowed mere months ago—
 14 before even allowing the government to provide notice of which portions of the CMS Report and Letter
 15 it intends to seek to admit at trial. Her request is premature at the very least. Furthermore, her
 16 897 Motion itself indicates that her proposed redactions are overbroad even for this stated purpose: she
 17 provides as an example a statement in the CMS Report that Theranos "lack[ed] documentation" for an
 18 assay not on the Bill of Particulars. 897 Mot. at 8. But an observation about lack of documentation is
 19 not challenging the accuracy or reliability of an assay. Defendant's motion sweeps far too broadly given
 20 the Court's guidance stated in its MIL Order.

21 Third, Defendant provides redactions of purported statements by Theranos employees that she
 22 submits the government has not sufficiently tied in an agency relationship to her so as to become an
 23 adopted admission. 897 Mot. at 8. However, the Court already found, with respect to an earlier letter
 24 that Theranos prepared and provided to CMS, that "the Government has sufficiently linked Holmes to
 25 the CMS Letter for purposes of introducing" the truth of it at trial. MIL Order at 25–27. The Court
 26 found that "Holmes's communications with Theranos employees and her involvement in the inspection
 27 process sufficiently links her to the [September 2015] CMS Letter[.]" *Id.* at 26. The same evidence also
 28 demonstrates that Holmes was sufficiently tied to Theranos employees responding to CMS's inquiries as

1 incorporated in the January 2016 CMS Letter and Report mere months after the September 2015 Letter,
 2 satisfying the adopted admissions standard for non-hearsay. At a minimum, accepting any of
 3 Defendant's proposed redactions on this basis would be premature at this time given that no witnesses
 4 have yet testified on this topic; the government anticipates that trial testimony will sufficiently tie
 5 Holmes to the CMS inspection and following conversations in a similar manner, as the Court requested
 6 when admitting statements of Theranos employees. *See* MIL Order at 94–97.

7 The results of Defendant's asserted bases for redactions demonstrate how absurd they are in
 8 total: Defendant asserts that she proposes "limited redactions" (897 Mot. at 3) but she seeks to redact
 9 approximately three-quarters of the 126-page CMS Report that the Court explicitly authorized to come
 10 in at trial. MIL Order at 16–20, 90. More specifically, if one were to omit the unredacted pages that
 11 generically describe the requisite qualifications of a laboratory technical supervisor—without any tie to
 12 Theranos—then little more than 15% of the CMS Report the Court deemed admissible would be usable
 13 by the government at trial.⁴ Not only does that effectively undo the Court's MIL Order admitting the
 14 report, but it also renders the document practically useless for the jury. Defendant does not explain how
 15 providing a heavily redacted version—with more than 80% of the document redacted—is helpful for the
 16 jury, particularly when the Court could simply give a limiting instruction to address most of Defendant's
 17 concerns.

18 In sum, the government urges the Court to deny outright Defendant's 897 Motion as essentially a
 19 request to reconsider the Court's MIL Order or, alternatively, to defer until the government has
 20 presented evidence allaying concerns Defendant raises and further supporting the Court's original
 21 inclination to admit the FDA and CMS Reports and the January 2016 CMS Letter.

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26 ⁴ Approximately 17 of the 35 pages without redactions in Defendant's version describe generically the
 27 requisite qualifications of a laboratory technical supervisor, but Defendant seeks to redact the relevant
 28 portion stating that Theranos failed to meet those standards. ECF No. 898-6 at 95–113. If one were to
 remove those 17 pages (from the numerator and denominator), then more than 83% of the remaining
 pages have suggested redactions by Defendant.

1 **IV. DEFENDANT'S MOTION TO EXCLUDE TESTIMONY FROM PHYSICIANS NO**
 2 **LONGER LISTED IN THE GOVERNMENT'S DISCLOSURE IS UNNECESSARY**

3 Defendant's 899 Motion seeks an unnecessary ruling from the Court to essentially reiterate what
 4 the Court held in its MIL Order. One of Defendant's motions *in limine* sought to exclude purported
 5 expert testimony of physician witnesses who treated patients who received inaccurate tests from
 6 Theranos as irrelevant, unfairly prejudicial, and untimely and improper expert testimony. *See* MIL
 7 Order at 47, 52 (citing ECF No. 561). The Court disagreed with the vast majority of Defendant's
 8 motion, finding the proposed testimony relevant and not unduly prejudicial (so long as the government
 9 does not elicit testimony about "the potentially catastrophic medical consequences that could follow
 10 from inaccurate blood tests"). *Id.* at 53–54. The Court explicitly held that the physicians will be
 11 allowed to "provide general background on a test, including what it is used for, when it is prescribed,
 12 and what medical decisions may flow from the results." *Id.* at 54. The Court held that physicians
 13 should avoid using the phrase "lab error" when describing inaccurate results, but otherwise held "that a
 14 physician may testify about her patients' test results and her conclusions about those results as a matter
 15 of fact, not opinion, even where they involve an explanation of the witness's medical judgment." *Id.* at
 16 52–53. The Court expressly stated that it did not need "a *Daubert* hearing to assess these physicians'
 17 ability to offer what is essentially factual testimony." *Id.* at 53. Finally, the Court turned to Defendant's
 18 assertion that the government provided inadequate Rule 16 disclosures, noting the government's
 19 position that it had "provided the Defendant with all of the information available to it," and relied on the
 20 government's representation that it would timely supplement the disclosures. *Id.* at 54–56; *see also*
 21 5/4 Tr. at 104:12–108:7 (government providing explanation for difficulty obtaining additional
 22 information from witnesses, including some of the physicians' involvement in helping with COVID-19
 23 vaccinations).

24 Defendant's 899 Motion accurately quotes the conclusion of the Court's order, denying her
 25 motion *in limine* to exclude testimony from these physicians, which allowed Defendant "Holmes to
 26 renew her motion to exclude [physician] expert testimony 'should the Government fail to provide
 27 updated disclosures in advance of trial.'" 899 Mot. at 3 (quoting MIL Order at 56). But Defendant's
 28 motion goes on to confirm that the government did, indeed, provide the updated disclosures that

1 Defendant requested within the timeframe she requested. *Id.* at 3–5. Defendant’s motion recounts how
 2 her counsel asked the government to provide supplemental expert-physician disclosures with more detail
 3 by July 30, 2021, and how the government agreed to and met that deadline. *Id.* at 4; *see also* ECF No.
 4 900, 900-1, 900-2, 900-3, 900-4. Thus, the sum and substance of Defendant’s 899 Motion seems to ask
 5 the Court to issue a ruling ordering the government to abide by the statements it made in its MIL filings,
 6 at the MIL hearing, and its compliance with the Court’s MIL Order.

7 There is no need for the Court to order the government to abide by its supplemental disclosures.
 8 Furthermore, as discussed below with respect to Dr. Das, the parties frequently differ in their views of
 9 what constitutes expert testimony and any blanket ruling on this topic could potentially be spun into a
 10 broader prohibition that the government strenuously objects to. Any blanket ruling from the Court on
 11 this motion is unnecessary given its MIL Order and premature given no facts have changed in a relevant
 12 manner since the Court’s MIL Order that would justify another order on the same topic.

13 **V. THE COURT SHOULD DENY OR DEFER DEFENDANT’S MOTION TO STRIKE
 14 DR. DAS’S EXPERT TESTIMONY BECAUSE—TO THE EXTENT IT CONSTITUTES
 15 EXPERT TESTIMONY—THE GOVERNMENT TIMELY DISCLOSED IT**

16 The Court should deny Defendant’s 892 Motion outright or, alternatively, defer it until after
 17 hearing Dr. Das’s testimony at trial. The government submits the expected testimony of Dr. Das
 18 constitutes percipient, not expert testimony. To the extent the Court disagrees, the government provided
 19 timely notice of the substance of Dr. Das’s expected testimony to Defendant and she has not suffered
 any prejudice from the allegedly late disclosure of Dr. Das as potential expert witness.

20 **A. Summary of Dr. Das’s Expected Testimony**

21 The summary of the expected testimony of Dr. Kingshuk Das, as provided by the government to
 22 Defendant in the form of memoranda of interviews that took place in February and June 2021, consists
 23 of the following: Dr. Das stated that he was hired in winter 2015 / spring 2016 as Theranos’s Newark
 24 Lab Director by Defendants Holmes and Balwani in part to respond to questions from CMS. ECF No.
 25 727-2 (memorandum of interview of Dr. Das on February 1, 2021). He worked as a contractor and then
 26 full-time employee at Theranos from December 2015 until he was laid off in June 2018. *Id.* Dr. Das
 27 also stated that, while employed as Theranos’s Lab Director, he “conducted a Six Sigma analysis of the
 28 Edison data and concluded the Edison devices did not perform well, and the accuracy and precision did

1 not meet the level needed for clinical testing.” *Id.* Indeed, he stated that “even using a fairly low bar,
 2 none of the Edison tests passed an acceptable level.” *Id.* Dr. Das said during the government’s
 3 interview that he attempted to raise these concerns with Defendants Holmes and Balwani, but received
 4 “some push back” and was told this was a “quality systems issue” and “not a device issue[.]” *Id.*
 5 Dr. Das disagreed and decided to void all of the Edison test results. *Id.* He will testify that he was
 6 required as lab director at Theranos to do so because the assays were unacceptable for clinical testing.
 7 ECF Nos. 727-2, 846-2. Dr. Das also had regular meetings with Defendant Holmes while he was
 8 employed at Theranos; however, when he would inform her of the issues with the Edison, the
 9 “conversations did not go well.” ECF No. 727-2. Dr. Das “believed he documented his work [and] this
 10 information should be contained in the contents of his Theranos computer hard drive.” *Id.*

11 As this Court noted in its MIL Order, Dr. Das ultimately responded on behalf of Theranos to
 12 CMS in a letter describing Theranos’s remediation efforts in response to CMS’s inspection and initial
 13 findings. MIL Order at 32. Dr. Das told the government in his second interview that he and his team
 14 “concluded [CMS inspectors] were ‘100%’ correct with their deficiency findings.” ECF No. 846-2
 15 (memorandum of interview of Dr. Das on June 7, 2021). Dr. Das also described in more detail what
 16 Sigma metric calculations involve, how one calculates them, and what the scores mean. *Id.* In addition,
 17 Dr. Das described what certain assay validation documents reflected, including that results for a
 18 particular sodium assay were “poor” and why the reference ranges were incorrectly determined. *Id.* He
 19 clarified that when he referred to “all TSPU assay results” he meant it as a term “interchangeable with
 20 Edison immunoassays.” *Id.*

21 **B. The Substance of Dr. Das’s Testimony is Percipient Not Expert Testimony**

22 Contrary to Defendant’s assertion that the substance of Dr. Das’s expected testimony
 23 “undoubtedly” includes expert testimony (892 Mot. at 6), the government submits Dr. Das will testify as
 24 a percipient witness regarding what he observed in his role as Theranos’s Newark Lab Director from
 25 early 2016 until mid-2018 and thus no expert disclosure was even required. Indeed, the government
 26 indicated in its supplemental disclosure to Defendant that “it is not necessary” to disclose Dr. Das as a
 27 potential expert witness, but provided that notice once it was alerted to the Defendant’s potentially
 28 differing view. ECF No. 893-1; *see* ECF No. 847 at 8 n.4.

1 The government asserts its position regarding Dr. Das's expected testimony aligns with the
 2 Court's ruling on several similar motions where Defendant asserted that potential government fact
 3 witnesses should be considered experts. Specifically, the Court, in essence, has already held similar
 4 expected testimony is fact testimony—not expert testimony—albeit with respect to another Theranos
 5 lab director, Dr. Adam Rosendorff. MIL Order at 75–78. Defendant sought to exclude certain proposed
 6 testimony from Dr. Rosendorff, an earlier Theranos lab director, for lack of expert support. *See* MIL
 7 Order at 75–78. “The Court [did] not agree” in part because “Dr. Rosendorff’s background as a
 8 laboratory director gives him a sufficient basis on which to present his observations and beliefs about
 9 Theranos’ use of [disputed lab practices] and his experience employing the method[s].” MIL Order at
 10 76; *see also* 5/6 Tr. at 74:11–80:8. The Court also found the evidence relevant and not unduly
 11 prejudicial. MIL Order at 75. Defendant’s motion specifically challenged Dr. Rosendorff’s expected
 12 testimony regarding Theranos’s use of “reference ranges”—notably a topic that Dr. Das also recalls as a
 13 concerning practice at Theranos. *Id.* at 75, 77; ECF No. 846-2 at 4. In its order denying Defendant’s
 14 motion, the Court went on to hold that, “[f]or reference ranges, the Court also does not believe evidence
 15 the Government intends to offer on this topic requires expert analysis.” MIL Order at 77. “This
 16 testimony is based on Dr. Rosendorff’s percipient observations while at Theranos as well as his
 17 judgment and experience as a certified laboratory director. . . . [Thus,] the introduction of a scientific
 18 basis and methodology pursuant to Rule 702 is not needed.” *Id.* So too with Dr. Das’s expected
 19 testimony. The Court’s order on Defendant’s motion *in limine* easily extends to Dr. Das’s expected
 20 testimony, bolstering the government’s view that his testimony is that of a percipient—not expert—
 21 witness.

22 The Court made similar findings with respect to other motions made by Defendant that touched
 23 upon this same topic. For example, as discussed above, the Court held that proposed testimony of
 24 physicians who treated patients that received an inaccurate Theranos blood test is relevant and not
 25 unduly prejudicial (with express limitations to which the government will adhere). MIL Order at 47–54.
 26 On the same topic, the Court specifically held “that a physician may testify about her patients’ test
 27 results and her conclusions about those results as a *matter of fact, not opinion, even where they involve*
 28 *an explanation of the witness’s medical judgment.*” *Id.* at 52–53 (emphasis added). In addition,

1 Defendant sought to exclude Dr. Rosendorff's testimony that Theranos's use of the Edison was not
 2 compliant with industry standards and government regulations as impermissible legal opinion and
 3 irrelevant and prejudicial. *See* MIL Order at 70–71; 7/4 Tr. at 165:20–171:22. The Court disagreed and
 4 held that the proposed testimony is relevant and not unduly prejudicial, and as such the government may
 5 introduce "statements made to Holmes which concerned perceived violations of industry standards and
 6 government regulations" to show Defendant's state of mind, accompanied by a curative instruction by
 7 the Court to that effect. MIL Order at 70–72.

8 These rulings apply with equal force to the expected testimony of Dr. Das. Dr. Das was hired by
 9 Defendants Holmes and Balwani as Theranos's Newark Lab Director⁵ in large part to respond to
 10 questions from CMS connected with the agency's inspection of Theranos's Newark laboratory. ECF
 11 No. 727-2 at 2. Theranos pointed to the hiring of Dr. Das—as well as his laudable experience and
 12 qualifications—as an example of the seriousness with which it took CMS's initial report. ECF No. 583-
 13 1 at 2 (Bates number THER-0534700, which is the document included with the memorandum of the
 14 interview of Dr. Das on February 1, 2021). Within the scope of his duties as lab director, and while
 15 attempting to respond to CMS as he was hired for his expertise to do, Dr. Das observed concerns with
 16 certain lab practices—in particular with Theranos's proprietary Edison device—and communicated
 17 those concerns to Defendant Holmes. *See* ECF Nos. 727-2, 846-2. At its core, that is fact witness
 18 testimony. Indeed, Dr. Das's proposed testimony about the accuracy and reliability of Theranos's
 19 Edison assays as he was working on responding to the CMS audit and resulting questions falls into the
 20 same category already ruled upon by the Court—fact testimony that may involve an explanation of his
 21 professional judgment as a lab director. *See* MIL Order at 47–54, 70–72, 75–78. Defendant herself has
 22 equated Dr. Das's testimony with that of Dr. Rosendorff and the doctor-physician witnesses when
 23 claiming prejudice from lack of access to the LIS database. *See* ECF No. 850 at 14. The reasoning in
 24 the Court's MIL Order should apply to Dr. Das as well, and thus Defendant's motion to strike should be
 25 denied outright for the same reasons expressed in the Court's prior order.

26
 27
 28 ⁵ The parties substantially agree on the duties and responsibilities of a lab director. *See* 5/4 Tr. at
 168:18–170:5, 175:12–21.

1 Defendant's assertions to the contrary lack merit. Defendant asserts both that she cannot
 2 determine what the underlying bases for Dr. Das's opinions and conclusions are and that the bases are
 3 improper because they are similar to the bases for the government's retained expert, Dr. Stephen Master.
 4 892 Mot. at 7–10. That Dr. Das used a mathematical calculation—called the Sigma metric—to
 5 determine whether Theranos's Edison devices were performing accurately and reliably such that the
 6 devices should be used to analyze patient samples of blood, which happens to be one of several well-
 7 established methods used by experienced and qualified lab directors, does not move his testimony from
 8 the percipient realm into the expert realm. *See* ECF Nos. 846-2, 842-1 at 2 (Dr. Master's supplemental
 9 expert report describing Sigma calculation). Dr. Das's expected testimony is that based on the data he
 10 reviewed at the time—namely, business records of Theranos or documents he created or reviewed—he
 11 concluded all of Theranos's Edison tests did not pass even “the lowest bar.” ECF No. 846-2 at 2–3.
 12 Just as with Dr. Rosendorff, the government submits such testimony falls within the Court's order that
 13 “the Government cannot use this evidence to establish Theranos was violating industry standards
 14 without proper expert opinion,” (which the government believes Dr. Master will provide), but “the jury
 15 can consider what decisions Holmes and Theranos made about certain disclosures [relating to lab
 16 practices] when evaluating Holmes' intent and the alleged scheme to defraud.” MIL Order at 78.

17 Defendant also asserts that she cannot sufficiently cross-examine Dr. Das because he does not
 18 identify which assays he reached this conclusion based on, because Dr. Das relied on a draft of a
 19 document without identifying the final version, and because Defendant does not have access to the same
 20 LIS data that Dr. Das would have been relying on at the time he formed his conclusions. 892 Mot. at 7–
 21 10. These too lack merit. First, Dr. Das clearly said *all* TSPU/Edison assays and the PT/INR assay,
 22 thereby falling within those that the government has identified in the Third Superseding Indictment and
 23 the Bill of Particulars. ECF No. 469 ¶ 16; MIL Order at 79 (noting Bill of Particulars listed same assays
 24 as TSI). Second, it is irrelevant whether Dr. Das relies on a Theranos business record that is a draft
 25 response to CMS to refresh his recollection. *Compare* ECF No. 893-4 at 2, *with* ECF No. 583-1 at 14
 26 (similar format in response to earlier CMS letter). Finally, Defendant again laments the loss of the LIS
 27 database in part because she cannot now, in present day, use that data to reconstruct some other,
 28 purportedly rosier picture than what the lab directors such as Dr. Das viewed at the time with the

1 relevant data in front of them, while performing the duties that Defendants Holmes and Balwani hired
 2 them to do. *See* 892 Mot. at 10. But this Court recently held that “the potential usefulness of the LIS
 3 data is speculative” and not necessarily exculpatory. *See* ECF No. 887 at 8–15.

4 In sum, even if Defendant could access the underlying data and could locate an expert willing to
 5 opine today that Dr. Das’s interpretation is incorrect (in which case Defendant has not disclosed such an
 6 expert), it still would not change the fact that Dr. Das reached his conclusions *years ago*, while
 7 employed by Defendant at Theranos for the purpose of reviewing the data as he did. Access to the
 8 documentary bases for Dr. Das’s conclusions will not change his overall testimony—which confirms
 9 that his expected testimony is quintessential percipient fact witness testimony rather than expert
 10 testimony.

11 Ultimately, Defendant takes umbrage with the fact that every lab director who worked at
 12 Theranos during the relevant time period—who was provided access to relevant data—had serious
 13 concerns with the accuracy and reliability of Theranos’s technology and did not think it should be used
 14 to process patient blood samples. But that does not give Defendant the right to try now to challenge the
 15 qualifications and methodologies of the people *she* hired to do the job at the time. Furthermore, when
 16 the lab directors raised concerns to the executive level of the company, they were dismissed or
 17 contradicted without support. *See* ECF No. 727-2. If support existed in the moment to undermine the
 18 conclusions of lab directors like Dr. Das, then it would exist elsewhere in the voluminous discovery
 19 produced in this case and prior related litigation and investigations, or other witnesses would be willing
 20 to testify to that effect. And Dr. Das identified where the files that supported his conclusions reside—
 21 left firmly within Theranos’s control. ECF Nos. 727-2 at 4, 846-2 at 3. Thus, Defendant should have all
 22 she needs to cross-examine Dr. Das on his percipient testimony, even if it is based on his background
 23 and expertise.

24 **C. The Government Timely Disclosed the Substance of Dr. Das’s Testimony**

25 The government timely disclosed the substance of Dr. Das’s testimony more than six months
 26 before trial is currently set to begin and provided notice to the Defendant pursuant to Federal Rule of
 27 Criminal Procedure 16(a)(1)(G) approximately one month after Defendant requested it.
 28 Rule 16(a)(1)(G) states: “*At the defendant’s request*, the government must give to the defendant a

written summary of any testimony that the government intends to use under Rules 702, 703, or 705 of the Federal Rules of Evidence during its case-in-chief at trial.” Fed. R. Crim. P. 16(a)(1)(G) (emphasis added). The written summary must describe the witness’s opinions and the bases and reasons for those opinions. *Id.* As this Court acknowledged in its MIL Order, Rule 16(a)(1)(G) imposes this requirement “to minimize surprise that often results from unexpected expert testimony, [to] reduce the need for continuances, and to provide the opponent with a fair opportunity to test the merit of the expert’s testimony through focused cross-examination.” ECF No. 798 at 54–55 (quoting Fed. R. Crim. P. 16 advisory committee’s note to 1993 amendment). The government’s disclosure in this case satisfied the letter and the purpose of Rule 16(a)(1)(G)’s disclosure requirements.

Defendant cannot claim surprise, a need for a continuance (*contra* 892 Mot. at 11), or that she has not had a fair opportunity to prepare to cross-examine Dr. Das considering she has had the substance of his expected testimony at trial for almost six months. The government first interviewed Dr. Das as a potential witness in this criminal case on February 1, 2021. ECF No. 893-2. The government submitted the substance of Dr. Das’s testimony to the Court and Defendant approximately two weeks after his initial interview took place on February 16, 2021. ECF Nos. 726 at 12 (USA Reply in support of motions *in limine*), 727-2 (Leach Declaration submitting memorandum of interview of Dr. Das on February 1, 2021 as Exhibit T in support of the government’s MIL Reply brief). Furthermore, the April 2016 letter to CMS—which was the sole document shown to Dr. Das by the government in his February 2021 interview⁶—was included as an exhibit to one of Defendant’s motions *in limine* and the Court quoted the letter from Dr. Das to CMS in its resulting order. ECF No. 583-1 (Bates number THER-0534700); MIL Order at 32. The substance of Dr. Das’s letter to CMS similarly stated his opinion at the time, while acting as Theranos’s Newark Lab Director, that “the laboratory is not satisfied with its old quality assessment’s program’s ability to effectively flag and promptly address QC imprecision, QC

⁶ Defendant insinuates—without proof—that the government has not produced the PowerPoint referenced in Dr. Das’s first interview. 892 Mot. at 9. But the interview demonstrates that Dr. Das was simply recalling his experience while working for Theranos and a time he disagreed with others regarding the performance capabilities of the Edison. ECF 727-2 at 2. The government did not show him this document, which is why it was not cited in the summary of the interview, but that does not mean the government has not otherwise produced it to Defendant. The government has produced all Theranos records relating to Dr. Das in its possession, custody, or control.

1 failures, and QC trends with the [Edison/TSPU]” and has determined to void all test results run on the
 2 Edison as a “corrective action.” *Id.* Thus, Defendant has been on notice of the substance of Dr. Das’s
 3 expected testimony for at least six months.

4 Furthermore, the government provided to the Court and Defendant the second memorandum
 5 summarizing the interview of Dr. Das on June 7, 2021, within two weeks of that interview. ECF Nos.
 6 846 at (USA Opposition to Defendant’s Motion to Suppress), 846-2 (Bostic Declaration submitting
 7 memorandum of interview of Dr. Das on June 7, 2021 as Exhibit T in support of the government’s
 8 opposition to Defendant’s motion to suppress). In late June, Defendant referenced Dr. Das’s expected
 9 testimony as an example of purported prejudice she faces from lack of access to the LIS database in
 10 Defendant’s Reply supporting her motion to suppress. ECF No. 850 at 14. And, at the hearing on
 11 Defendant’s motion to suppress, her counsel reiterated that Defendant would not be able to confront
 12 Dr. Das on “his recollection of what analyses he performed” without access to the LIS database, which
 13 Defendant asserted is the “kind of testimony that [the government] want[s] to put at issue.” 7/7/2021
 14 Hearing Transcript (“7/7 Tr.”) at 37:2–22, 39:22–40:4; *contra* 892 Mot. at 3:6–9 (asserting Defendant
 15 had no clue the government would elicit this type of testimony from Dr. Das). Thus, Defendant has
 16 been aware of the substance of Dr. Das’s expected testimony, as well as the government’s intent to use
 17 it, for almost as long as the government has been aware of such potential testimony.⁷

18 And, contrary to Defendant’s complaints regarding the government’s supplemental notice, it met
 19 the plain language requirements of Rule 16(a)(1)(G). As discussed above, it is the government’s view
 20 that Dr. Das’s testimony is that of a percipient, rather than an expert, witness. Nevertheless, on June 25,
 21 2021, Defendant indicated in an unrelated filing that she believed Dr. Das should not be permitted to
 22 testify about calculations he ran while employed by her at Theranos and opinions he reached at the time
 23 based on his expertise because the government had not identified him as an expert witness. ECF No.
 24

25
 26 ⁷ To the extent Defendant insinuates the government should have interviewed Dr. Das sooner (892 Mot.
 27 at 5), there is no obligatory order in which the government must interview potential witnesses. Dr. Das
 28 is one of multiple lab directors who worked at Theranos and he was employed toward the end of the
 period at issue in the Third Superseding Indictment. As relevant for purposes of this motion, once the
 government did interview Dr. Das, it promptly provided Defendant with the information it gathered
 during those interviews. *See* ECF Nos. 727-2, 846-2.

1 847 at 8 n.4. Within approximately one month of this—essentially defendant’s request for disclosure of
 2 Dr. Das as an expert witness pursuant to Rule 16(a)(1)(G)—the government provided that disclosure.
 3 ECF No. 893-1; *see* Fed. R. Crim. P. 16(a)(1)(G) (“*At the defendant’s request*, the government must
 4 give to the defendant a written summary of any [expert] testimony[.]” (emphasis added)). Moreover, the
 5 government’s supplemental disclosure was sufficient because it provided the witness’s expected
 6 opinions—as described in the two interview memoranda provided to Defendant months prior—as well
 7 as the bases and reasons for those opinions—namely, the calculations described in his interviews and
 8 business records of Theranos that either Dr. Das himself generated or that he would have had access to
 9 during the time of his employment in reaching his conclusions that he presented to Defendant and other
 10 Theranos executives. ECF No. 893-1.

11 In sum, Defendant’s 892 motion to strike Dr. Das’s testimony as untimely expert testimony seeks
 12 to elevate form over substance. She complains about the form of the government’s disclosure (892 Mot.
 13 at 7–10) but ignores that she received the substance more than six months before the start of her criminal
 14 trial. Notably, the government provided the supplemental disclosure approximately one month after
 15 learning that Defendant viewed Dr. Das’s testimony as potential expert testimony and prior to a deadline
 16 that Defendant endorsed as being sufficient in a related context for other fact-expert witnesses. *See*
 17 ECF No. 900-1.

18 **D. To the Extent Any of Dr. Das’s Testimony Could Be Considered Expert Testimony,
 19 Defendant Cannot Show She Was Prejudiced by the Timing of the Government’s
 Disclosure**

20 Defendant cannot demonstrate any prejudice that flows from the government’s supplemental
 21 disclosure on July 29, 2021, which incorporated the substance of testimony that Defendant had access to
 22 for months. Defendant mainly claims that the disclosure provided insufficient time to challenge
 23 Dr. Das’s proposed testimony through motions *in limine* or a *Daubert* motion. 892 Mot. at 4, 10–11.
 24 But, as described above, Defendant has filed motions *in limine* on topics broad enough to include
 25 Dr. Das’s expected testimony—which was known to Defendant at the time such motions were
 26 pending—and Defendant has prefaced her potential *Daubert* motion in this motion to strike. *Id.* at 10–
 27 11; *see* MIL Order at 47–54, 70–72, 75–78 (addressing motions overlapping with topics Defendant
 28 raises now against Dr. Das). The topics Defendant asserts she would raise in her contemplated *Daubert*

1 motion have either already been decided by the Court in favor of the government (*see* ECF No. 887
 2 regarding LIS database), or are pending a final ruling by the Court, such as the upcoming *Daubert*
 3 hearing of Dr. Master who will be discussing the Sigma metric calculation among others at length (*see*
 4 ECF No. 842-1). Furthermore, contrary to Defendant's assertion that she cannot effectively cross-
 5 examine Dr. Das, her motion provides several avenues of potential cross-examination. 892 Mot. at 11.
 6 Undoubtedly, she was able to identify these areas because Defendant has had the summaries of
 7 Dr. Das's expected testimony for months. Thus, Defendant cannot demonstrate any prejudice flowing
 8 from the government's supplemental disclosure, and Defendant has certainly not shown prejudice that
 9 would warrant the extreme measure of another continuance that she suggests (892 Mot. at 11:25).⁸

10 CONCLUSION

11 For the reasons stated above, the government respectfully requests that the Court deny outright
 12 or defer ruling on Defendant's 892, 895, 897, and 899 Motions.

13
 14
 15 DATED: August 12, 2021

Respectfully submitted,

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18 /s/ Kelly I. Volkar
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 26
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 28 ⁸ If the Court disagrees, the government notes that the Court could simply impose a lesser sanction such as requiring the government to wait until later in the trial to call Dr. Das to testify.